Serious Transfusion Incident Reporting program

Annual report 2014–15

blood matters

Australian Red Cross BLOOD SERVICE

VICTORIA State Government

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Serious Transfusion Incident Reporting program

Annual report 2014–15

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Acknowledgements

The Blood Matters program is a collaboration between the Victorian Department of Health and Human Services (the department) and the Australian Red Cross Blood Service (the Blood Service). It is founded on the expectation that providing relevant haemovigilance information will support the community by promoting better transfusion practice.

The Serious Transfusion Incident Reporting (STIR) program thanks the participating Victorian, Tasmanian, Australian Capital Territory and Northern Territory public and private health services for their contribution to the program.

Blood Matters recognises and appreciates the generous in-kind support of the STIR expert group, whose input was invaluable in reviewing the incidents, the report and providing recommendations.

Abbreviations, acronyms and definitions

ALI	acute lung injury
AML	acute myeloid leukaemia
ANZSBT	Australian and New Zealand society of blood transfusion
ATR	acute transfusion reaction
BNP	B-type natriuretic peptide
BP	blood pressure
CHF	congestive heart failure
CNS	coagulase-negative Staphylococcus
CVP	central venous pressure
DAT	direct antiglobulin test
DHTR	delayed haemolytic transfusion reaction
FNHTR	febrile non-haemolytic transfusion reaction
FFP	fresh frozen plasma
FY15	financial year 15 (1 July 2014 to 30 June 2015)
Hb	haemoglobin
HLA	human leucocyte antigen
HPA	human platelet antigen
HTR	haemolytic transfusion reaction
ID	identification
Ig	immunoglobulin
IBCT	incorrect blood component transfused
ICU	intensive care unit
LDH	lactate dehydrogenase
MCV	mean corpuscular volume
MET	medical emergency team
NBA	National Blood Authority
PCWP	pulmonary capillary wedge pressure
PPH	post-partum haemorrhage
PSE	potentially sensitising event
PTP	post-transfusion purpura
Rh	rhesus
RhD Ig	rhesus (D) immunoglobulin
SHOT	Serious Hazards of Transfusion
TACO	transfusion-associated circulatory overload
TAGvHD	transfusion-associated graft versus host disease
the Blood Service	Australian Red Cross Blood Service
the department	Department of Health and Human Services
TTI	transfusion-transmitted infection
TRALI	transfusion-related acute lung injury
PTP	post-transfusion purpura
VHIMS	Victorian Health Incident Management System
WBIT	wrong blood in tube

Executive summary

The Blood Matters Serious Transfusion Incident Reporting (STIR) system is a voluntary reporting system for a defined set of serious adverse events relating to transfusion in Victoria, Tasmania, Australian Capital Territory and Northern Territory. It includes clinical reactions and procedural events, including near misses, related to transfusion of fresh blood components.

STIR monitors these events and provides recommendations to improve transfusion safety for patients. It continues to provide validated data through the process of review by a group of clinicians, nurses and scientists with expertise in transfusion medicine.

This is the sixth report for the STIR program and the second annual report. It presents a summary and analysis of data from expert reviewers for the period 1 July 2014 to 30 June 2015, with associated recommendations for health services.

Health services should adopt these recommendations, and ensure they are implemented.

Fewer health services reported to STIR in this period (37 per cent of registered health services), with more withdrawn reports. This may be due to changes in STIR reporting, such as changes to wrong blood in tube (WBIT) reporting, or changes occurring within health services, such as change of staff and incomplete handover.

For health services that do not have access to transfusion experts, the STIR secretariat can provide advice and access to expert assistance.

Blood Matters regularly presents the data it collects to health services and at conferences/meetings (see Appendix 2).

Of concern, there are more procedural than clinical incidents reported to STIR in this financial year.

Clinical incidents often occur independent of good processes and may be unavoidable. In contrast, procedural errors highlight a lack of understanding or adherence to processes. Many procedural incidents can be avoided if good processes are in place and adhered to.

As in previous years, the report also includes a transfusion safety checklist designed to address the issues highlighted by these investigation reports. The checklist is a short and practical tool for health services to assess their own systems. It reflects areas and issues identified by the organisations and jurisdictions which contribute to STIR, as well as the recommendations of the expert group.

Key messages and recommendations

Clinical recommendations

1. Appropriate investigations of each reaction to determine probable reaction type and de-identified reports of these sent with the completed STIR investigation is important to the validation of reports received.
2. Unless required to treat life-threatening bleeding, a slow infusion rate should be used for all blood products to minimise the risk of reactions such as TACO and allergic reactions.
3. Clinicians should consider the use of pre-transfusion risk assessment tools for TACO to reduce the likelihood of TACO occurring.
4. Development of a regional or national database of antibodies, accessible to laboratories, may prevent re-exposure to antigen-positive units and consequent DHTR.

Procedural recommendations

5. Patient identification is important in all steps in the transfusion chain. This includes the confirmation of full name, date of birth and hospital number, or an alternative recognised system for identifying patients where patient identity has not yet been established, for all requests, communications and checks.
6. Health services need clear, unambiguous ordering processes for blood products, with particular attention given to the way prescriptions are written, for example using consistent terminology such as units, doses or bags to prevent confusion over what is being ordered and the dose required.
7. Where RhD immunoglobulin (Ig) is used there should be a process in place to ensure the documentation and communication of the patient blood group to all staff involved. Where an external pathology service result is used this must be documented clearly, accurately and appropriately. A validated report from an external laboratory is required, rather than a transcribed result in the patient medical record or referral letter.
8. Laboratory services need to consider alerts within the laboratory information system to highlight when blood of a group other than the patient's own is being issued. This should be in place for both ABO and RhD discrepancies to avoid inappropriate crossing of blood groups.

Transfusion safety checklist

Health services can use this transfusion safety checklist to measure compliance and support safety for transfusion recipients. The issues and areas addressed in the checklist are based on data received and analysed, leading to the recommendations by the STIR expert group.

Issue	Strategies to address the issue	Yes	No	WIP*	NA#
Patient identification	Complete and correct patient identification should be included in procedures and training for all staff involved in each step of the transfusion process.				
	Health services should have procedures in place to address patient identification issues for those most at risk, newborns and others unable to provide identification or be involved in the identification process.				
Laboratory standard operating procedures for blood bank	Use alerts to make staff aware they have chosen a blood product that is not of the patient's own group, such as 'The product blood group selected is compatible but not the first choice for the patient'. When taking orders for products or dispensing products, laboratories should encourage staff to request full patient identification for each communication or request.				
Blood product prescription	The prescription must be clear and unambiguous. Standardised terminology for blood components is not yet agreed nationally, but prescribers should be encouraged to avoid acronyms that may be ambiguous or misleading (ANZSBT 2011). Health services should standardise their prescribing processes using units, bags or doses.				
Management of transfusion reactions	Procedures should include who is responsible for reports to STIR and how these are followed up.				
Training and credentialling staff in transfusion practice	Training in transfusion should include transfusion reactions. The BloodSafe eLearning tool should be used along with a health service education program for transfusion practice. Information on the courses from BloodSafe eLearning Australia is available at: <www.bloodsafelearning.org.au/> The Blood Service also provides education on adverse event eLearning: <learn.transfusion.com.au/course/index.php?categoryid=17>				
Health service transfusion committee or equivalent	All adverse events involving blood should be reviewed by the reporting health service prior to submission to STIR. Ideally this review should be by either the health service transfusion committee or equivalent (if meeting prior to STIR submission date), or by the chair of the committee or a senior medical officer, outside of normal institutional meeting times.				

Introduction

The Blood Matters Serious Transfusion Incident Reporting (STIR) scheme is a system developed to assist health services to report haemovigilance data at both jurisdictional and national levels, with de-identified data from STIR provided to the National Haemovigilance report.

STIR aims to provide local information on the number and type of serious reactions that occur, and to collate and report on these reactions with recommendations for improvements for better, safer transfusion practice.

This is the second annual report produced. It covers the period 1 July 2014 to 30 June 2015. There are 92 health services registered with STIR across Victoria, Australian Capital Territory, Northern Territory and Tasmania, comprised of public (70 per cent) and private (30 per cent) health services. This report includes reports submitted from 34 of these health services (37 per cent reporting). STIR received 175 notifications, including incidents, reactions to blood components and near misses. There were 137 reports analysed, after events were withdrawn or excluded. These are termed validated investigations. Nine reports were re-categorised after expert review.

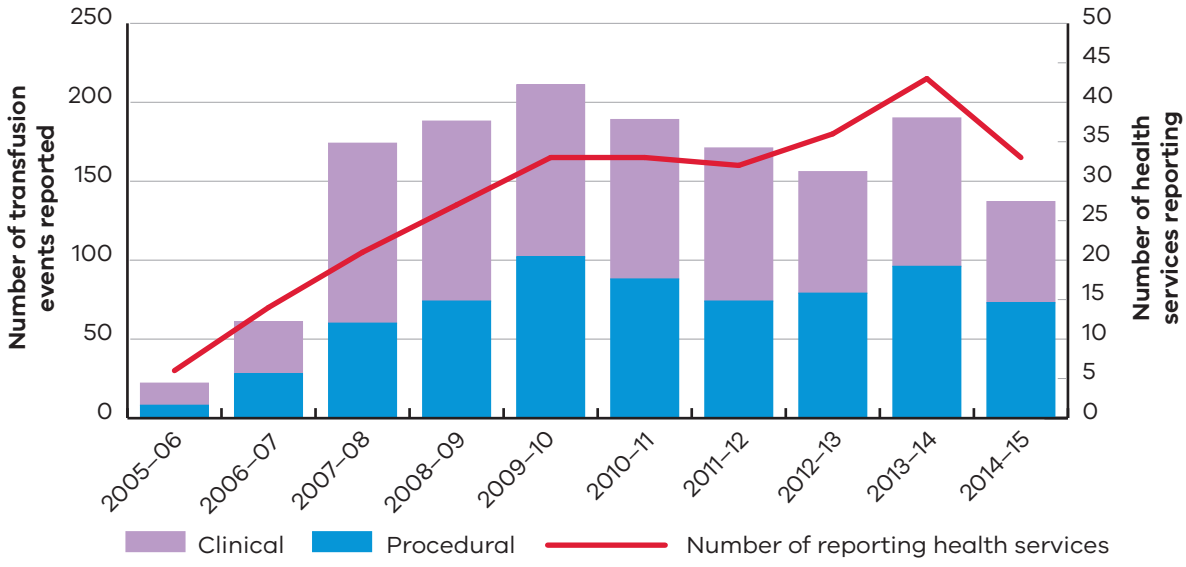
In this reporting period, we added new notification categories: incidents relating to RhD Ig administration and those relating to cell salvage. We report on these for the first time.

Reporting to STIR is not mandatory, and as such it is not expected that all reactions/events will be reported. This may be due to events not being recognised, staffing constraints, non-reporting health services or events that do not meet STIR reporting criteria.

Where possible we work with the Blood Service to reconcile reportable incidents such as transfusion related acute lung injury (TRALI) and transfusion-transmitted infections (TTI). When these reactions are reported, the reporter is reminded of the need to notify the Blood Service. However, reporting to STIR usually occurs retrospectively after an investigation to confirm the event.

The total number of validated clinical and procedural reports and health services reporting to STIR each financial year is outlined in Figure 1.

Figure 1: Number of validated clinical and procedural reports and health services reporting to STIR each financial year



Data for 2014–15

For the purposes of this report, STIR received 175 initial notifications, with 26 of these withdrawn prior to an investigation form being returned from the health service.

Eight investigation forms were not returned by the health services, and a further four reports were excluded after expert review, resulting in 137 validated investigations being included in this report.

Table 1 shows total blood issues data per jurisdiction in 2014–15. This data assists in providing an estimate of relative risk of transfusion related events, as outlined in Table 2.

Table 1: Total of blood issues per jurisdiction 2014–15

Products	Victoria	Tasmania	ACT	Northern Territory
Red cells	182,602	11,719	10,956	4,435
Platelets	34,114	2,256	1,550	831
Fresh-frozen plasma	30,785	1,723	1,624	685
Cryoprecipitate	22,218	1,343	1,749	966
Total	**269,719**	**17,041**	**15,879**	**6,917**

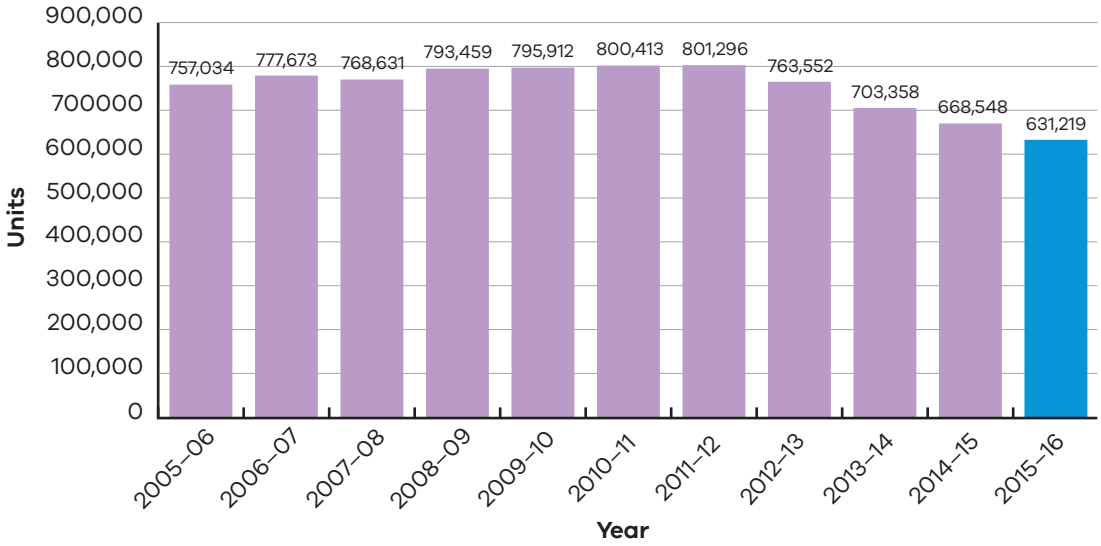
Table 2: Frequency of events per product issued in Victoria

Product	Blood issues (Victoria)	Validated events*	Frequency
Red cells	182,602	48	1:3726
Platelets	34,114	15	1:2436
FFP	30,785	5	1:6157
Cryoprecipitate	22,218	0	1:22,000

*Victorian notifications only

Demand for red cells has declined over the previous five years (see Figure 2), with a further decrease in demand of 5.6 per cent anticipated for 2015–16 (*Blood Service Annual Report 2014–15*). There has been some decrease in demand for fresh frozen plasma (FFP) and platelets also. Cryoprecipitate is the only product to be in increased demand. This may result in the reporting of fewer reactions related to red cell transfusion.

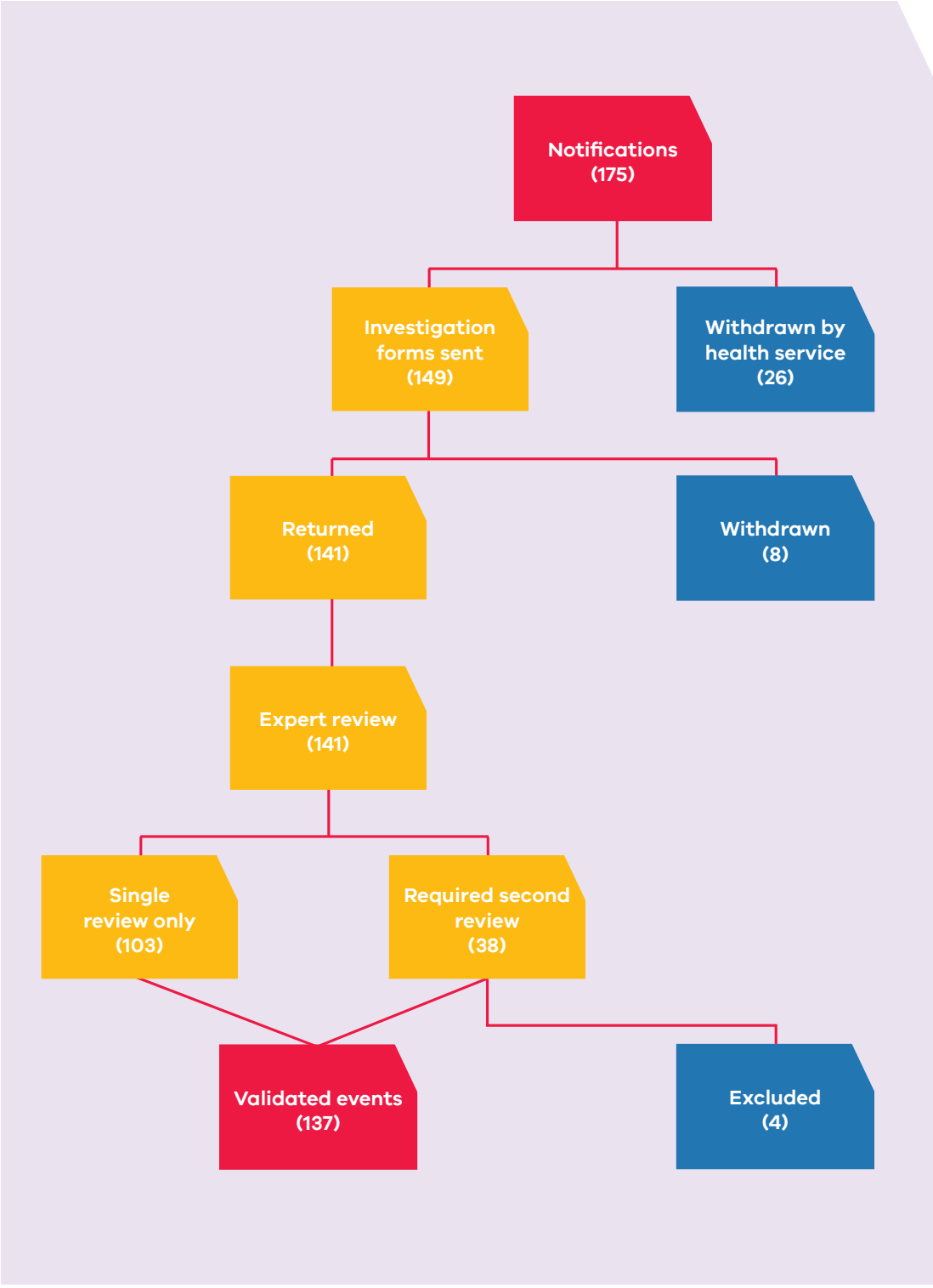
Figure 2: Annual red cell demand (national)



Method

Figure 3 shows the steps in the STIR reporting process, from notification through to validated events.

Figure 3: Steps in STIR reporting process



Withdrawn reports

Reports may be withdrawn by health services for a number of reasons as described in Table 3.

Reports that are duplicates, not in scope (for example specimen-labelling issues that should be picked up by zero tolerance, or reaction to intravenous immunoglobulin) or not related to transfusion are generally withdrawn prior to an investigation form being sent out to the health service.

Occasionally investigation forms are not returned. Typically this occurs where there is a change of staff and incomplete handover of outstanding reports, or may indicate a problem with the reporting or investigation arrangements in those organisations.

Table 3: Reasons for withdrawal of reports

Financial year	Duplicate	Not in scope	Deemed not transfusion related	Not completed	Expert review excluded	Total
2012–13	2	4	0	4		10
2013–14	1	6	4	16		27
2014–15	9	11	6	8	4	38

Validation steps

The STIR process includes steps to ensure the validity of data provided.

All reports are independently reviewed by a member of the STIR expert group, which is made up of interested parties with expertise or experience in the area of transfusion. Where the expert reviewer identifies a significant discrepancy between their classification and classification identified by the reporting health service, a second review is undertaken.

If consensus cannot be reached with the second review, the expert group as a whole reviews the report to determine incident type and severity.

Occasionally information available to the experts is incomplete or conflicting. In some reports, test results that would help to confirm or eliminate a possible diagnosis are not available. In these cases, a definitive classification of the reaction may not be possible.

Some adverse events may be excluded from the report by the reviewer if the information supplied by the health service does not support the likelihood of a transfusion reaction. Four events fit this category in this reporting period. In addition, two reports supported the likelihood of a transfusion reaction, but were deemed not assessable in regards to imputability and severity.

Re-categorisation following expert review

Following expert review, four acute transfusion reaction (ATR) events were excluded as they were determined to be unrelated to the transfusion. In addition, seven events were reclassified, as shown in Table 4.

Table 4: Incident type following expert review

Incident type at notification	Incident type following expert review						
	ATR						
	Allergic	FNHTR	Delayed	Other	**TRALI**	TACO	**Total**
ATR							
Allergic		1					**1**
FNHTR				1			**1**
Delayed		1					**1**
Other		1					**1**
TRALI						1	**1**
TACO	2						**2**
Total	**2**	**3**	**0**	**1**	**0**	**1**	**7**

Expert reviewers also assess the severity of the clinical reactions reported. In 24 events the severity rating (SR) was increased following expert review (Table 5).

Table 5: Changes to severity rating following expert review

		Severity rating following expert review		**Total**
Severity rating at notification		SR2	SR3	
ATR	SR4	4	14	**18**
Delayed	SR4		1	**1**
IBCT	SR4		3	**3**
TACO	SR4		2	**2**
Total		**4**	**20**	**24**

See Appendix 3 for definition of severity ratings.

Demographics

Table 6: Demographics for all validated reports

Incident type	Number (%)	Median age (range)	Gender	
			Male	Female
Clinical reports				
FNHTR	19 (30)	75 years (9–89)	63%	37%
Allergic	21 (33)	51 years (3–74)	52%	48%
Acute haemolytic	–	–	–	–
ATR (other causes)	5 (8)	57 years (49–75)	20%	80%
Bacterial sepsis	–	–	–	–
TACO	9 (14)	74 years (48–92)	56%	44%
TRALI	–	–	–	–
Delayed haemolytic	10 (15)	73 years (31–89)	40%	60%
TAGvHD	–	–	–	–
PTP	–	–	–	–
Clinical subtotal	**64**	**67 years (3–92)**	**52%**	**48%**
Procedural reports				
IBCT	6 (8)	49.5 years (0–63)	67%	33%
WBIT	56 (77)	35.5 years (0–94)	45%	55%
RhD immunoglobulin	6 (8)	31 (28–38)	0%	60%
Cell salvage	–	–	–	–
Near miss	5 (7)	54 years (0–87)	40%	60%
Procedural subtotal	**73**	**36 years (0–94)**	**42%**	**58%**
Total	**137**	**54 years (0–94)**	**47%**	**53%**

As in previous years slightly more women than men are represented in the STIR reports received, with allergic reactions being the most common clinical reaction reported, and WBIT the most common procedural event (Table 6).

Red cells are the most common blood product associated with reported reactions. The one exception to this is in allergic reactions, where more reports related to platelets (48 per cent) than any other product (Table 7).

Table 7: Blood product implicated by validated incident type

	Blood product type					
Incident type	Red cells	Platelets	FFP	Cryoprecipitate	Multiple products	Other
Clinical reports						
FNHTR	17 (89%)	–	–	–	2 (11%)	–
Allergic	5 (24%)	10 (48%)	3 (14%)	–	2 (10%)	1 (5%)
Acute haemolytic	–	–	–	–	–	–
ATR – other causes	3 (60%)	1 (15%)	1 (15%)	–	–	–
Bacterial sepsis	–	–	–	–	–	
TACO	4 (44%)	2 (18%)	1 (11%)	–	2 (18%)	–
TRALI	–	–	–	–	–	–
Delayed haemolytic	10 (100%)	–	–	–	–	–
TAGvHD	–	–	–	–	–	–
PTP	–	–	–	–	–	–
Clinical subtotal	**39 (61%)**	**13 (20%)**	**5 (8%)**	**–**	**6 (9%)**	**1 (2%)**
Procedural reports						
IBCT	4 (67%)	–	1 (17%)	–	1 (17%)	–
WBIT	5 (9%)	–	–	–	–	51 (91%)
RhD immunoglobulin	–	–	–	–	–	6 (100%)
Cell salvage	–	–	–	–	–	–
Near miss	4 (80%)	1 (20%)	–	–	–	–
Procedural subtotal	**13 (18%)**	**1 (1%)**	**1 (1%)**	**–**	**1 (1%)**	**57 (78%)**
Total	**52**	**14**	**6**	**0**	**7**	**58**

It is encouraging to see that serious reactions and incidents continue to be reported to the highest levels of governance within health services, with all reports confirming that the incident had been or was to be reviewed as described in Table 8.

No deaths due to transfusion reaction were reported in this period. However, seven patients required admission to an intensive care unit due to the transfusion reaction, with one of these patients needing haemodialysis (Table 9).

Table 8: Incident reviewers within the health service

Incident type	Hospital transfusion committee or equivalent	Chief medical officer or other appropriate senior medical officer	Hospital clinical governance unit or equivalent	At least one type of review undertaken
Clinical reports				
FNHTR	19	4	5	19 (100%)
Allergic	21	3	5	21 (100%)
Acute haemolytic	–	–	–	–
ATR – other causes	5	–	–	5 (100%)
Bacterial sepsis	–	–	–	–
TACO	9	5	6	9 (100%)
TRALI	–	–	–	-
Delayed haemolytic	9	3	2	10 (100%)
TAGvHD	–	–	–	–
PTP	–	–	–	–
Clinical subtotal	**63**	**15**	**18**	**64 (100%)**
Procedural reports				
IBCT	6	3	3	6 (100%)
WBIT	51	15	28	56 (100%)
RhD immunoglobulin	6	3	3	6 (100%)
Cell salvage	–	–	–	–
Near miss	5	3	4	5 (100%)
Procedural subtotal	**68**	**24**	**38**	**73 (100%)**
Total	**131**	**39**	**56**	**137 (100%)**

*More than one reviewing body may be checked for each incident.

Outcomes

Table 9: Outcome for the patient this admission, post-transfusion (multiple answers may be given)

Patient outcome	ATR (n = 45)	Delayed (n = 10)	TACO (n = 9)	IBCT (n = 6)
No increase in care (apart from the transfusion incident investigations)	10	3	0	5
Temporary increase in care	29	5	8	0
Permanent increase in care	0	0	0	0
Increase length of stay	6	1	4	0
ICU admission due to transfusion reaction	4	1	3	0
Haemodialysis/haemofiltration	1	1	0	0
Death due to transfusion reaction	0	0	0	0
Death not due to transfusion reaction	3	1	0	0
Outcome not recorded	2	0	0	0
Not yet discharged	0	0	0	1

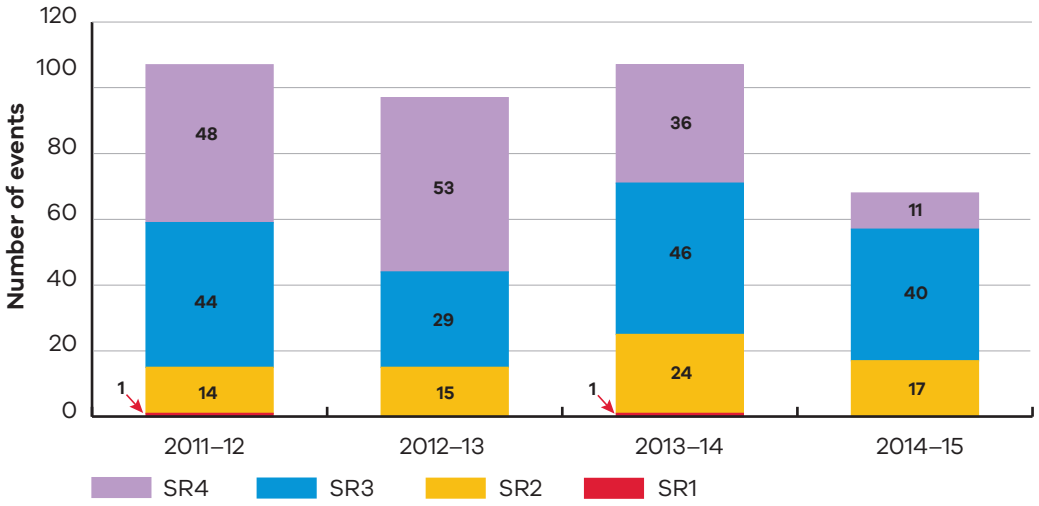
*For all reports except near miss, RhD immunoglobulin, TaGVHD and WBIT events.

Severity rating

For this reporting period, there were no SR1 events. These are events that resulted in, or had the realistic potential to result in, an unexpected death or a permanent and disabling injury or psychological harm to a person.

There were also fewer SR4 events reported, which may reflect health services only reporting serious events that meet the criteria set out by STIR (Figure 4).

Figure 4: Severity ratings



Shown for ATR, delayed, TACO and IBCT only

Clinical reports

Figure 5 shows the number of clinical reactions reported to STIR in 2014-15, with Figure 6 comparing acute transfusion reactions reports with previous years' reporting

Figure 5: Clinical reactions reported in 2014–15

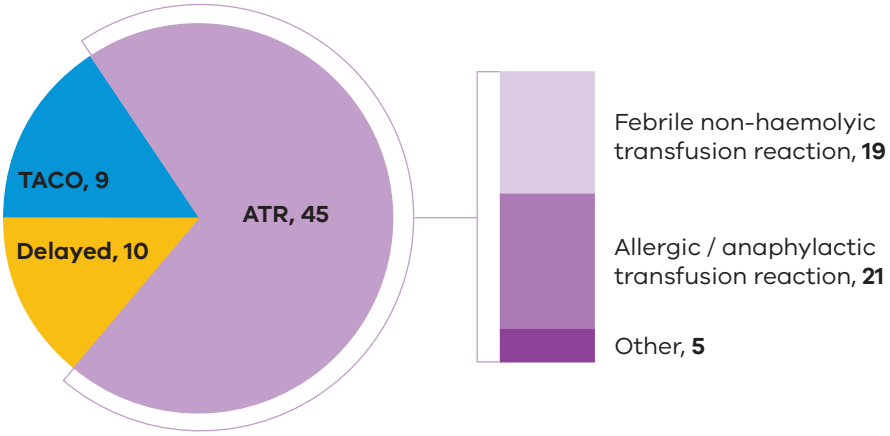
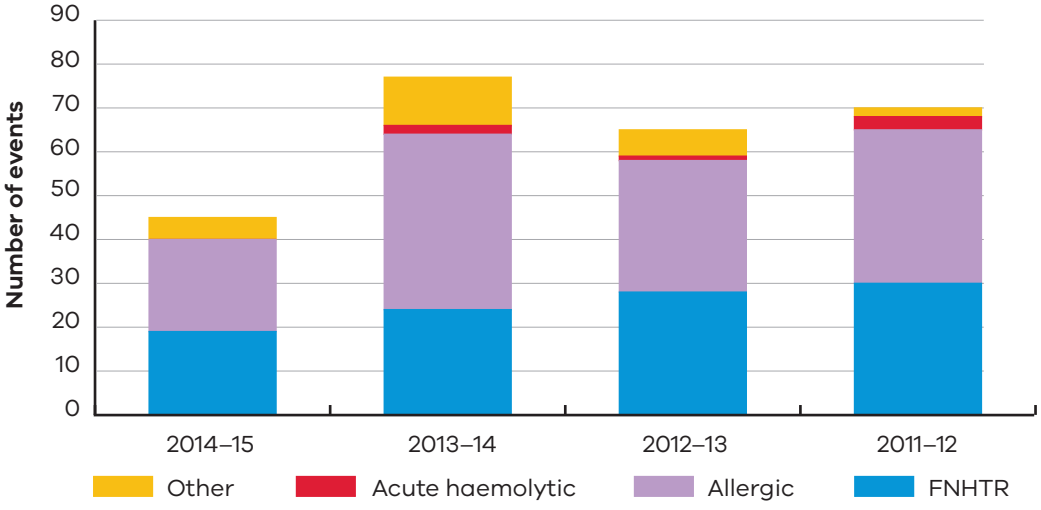


Figure 6: Comparison with previous years' ATR reviewed reports



Febrile non-haemolytic transfusion reaction (FNHTR)

Data summary – validated data Febrile non-haemolytic transfusion reaction, n = 19			
Gender		**Time of transfusion**	
Male	12	In hours (8 am to 8 pm)	15
Female	7	Out of hours (8 pm to 8 am)	4
Age		**Imputability**	
< 1 year	0	Certainly	
1–18 years	3	Probably	7
19–29 years	0	Possibly	12
30–49 years	1	Excluded	
50–69 years	2	Not assessable	
70–79 years	10	**Severity**	
80+ years	3	SR1: unexpected death or a permanent and disabling injury	
Blood product implicated			
Red cells	17	SR2: temporary loss of function	2
Platelets		SR3: increased treatment, but no increased length of stay	12
FFP			
Cryoprecipitate		SR4: no injury or minor requiring only first aid treatment	5
Multiple products	2		
		Not assessable	

STIR guideline

FNHTRs with the following characteristics should be reported to STIR:

Fever (> 38.5° C or an increase of 1.5° C above baseline), occurring during or within four hours of the transfusion with one or more of the following:

- chills/rigor
- headache
- nausea/vomiting.

Generally patients present with an unexpected temperature rise during or shortly after transfusion. This is usually an isolated finding. Occasionally the fever is accompanied by chills, rigors, increased respiratory rate, change in blood pressure, anxiety and/or headache.

These symptoms may also occur in other more serious transfusion reaction types.

FNHTR is a diagnosis of exclusion, and it is important to ensure that a more serious reaction is not being missed.

FNHTRs occur in 0.1 per cent to one per cent of transfusions with the advent of leucocyte depletion of blood products (Roback 2011). One study demonstrated a decrease in FNHTRs post leucodepletion from 0.37 per cent to 0.19 per cent for all transfusions (King et al. 2004).

Release of cytokines by white cells and accumulation during storage of cellular components was thought to be the most common event leading to symptoms of FNHTRs (Roback 2011), however pre-storage leucodepletion has reduced this risk.

Management of FNHTR includes stopping the transfusion and ensuring a more serious reaction, such as a haemolytic reaction is not occurring. Paracetamol may be administered to treat fever if required and pethidine, in small doses, may be used to treat rigors if severe.

Case study: Reported as FNHTR, determined to be related to other causes

A 77-year-old man with colorectal cancer and associated anaemia was transfused a unit of red cells.

Approximately 90 minutes into the transfusion, he developed fever without other signs or symptoms. Testing of the post-transfusion specimens showed no change in results for both patient and unit, and the unit to be serologically compatible.

The post-transfusion antibody screen was positive, pre-transfusion it was negative, with no history at the health service prior to this event. Bacterial culture of both patient and blood unit were negative.

It would appear in this case that the fever described was attributable to the urinary tract infection identified on urine culture, and this was determined not to be a transfusion reaction.

Reporting of complete investigations by the health service meant that transfusion reaction could be excluded.

It is often difficult to attribute fever to a particular cause when investigations regarding this are not performed and/or results not available.

Allergic

Data summary – validated data Allergy, n = 21			
Gender		**Time of transfusion**	
Male	11	In hours	19
Female	10	Out of hours	2
Age		**Imputability**	
< 1 year	0	Certainly	7
1–18 years	7	Probably	9
19–29 years	1	Possibly	5
30–49 years	2	Excluded	
50–69 years	7	Not assessable	
70–79 years	4	**Severity**	
80+ years	0	SR1: unexpected death or a permanent and disabling injury	
Blood product implicated			
Red cells	5	SR2: temporary loss of function	8
Platelets	10	SR3: increased treatment, but no increased length of stay	11
FFP	3		
Cryoprecipitate	0	SR4: no injury or minor requiring only first aid treatment	2
Multiple products/other	3		
		Not assessable	

STIR guideline

Allergic reactions

These reactions occur when the most likely cause of the allergy is the transfusion. Consider other causes for the allergic reaction, for example drug reactions.

Report reactions where one or more of the following occur within four hours of transfusion; and where there is no evidence of significant hypotension:

- rash
- allergic dyspnoea (stridor, cyanosis, wheezing)
- angioedema
- urticaria.

Anaphylactoid/anaphylaxis reaction

An allergic reaction with associated hypotension (drop in systolic BP > 30 mmhg) during or within four hours of transfusion.

Alternatively this may include intractable hypotension or shock with loss of consciousness associated with transfusion and excluding any other identifiable cause.

Mild allergic reactions (urticaria and hives) occur in one to three per cent of transfusions. These reactions may be associated with mild upper respiratory or gastrointestinal symptoms. Patients with an atopic history are more likely to experience allergic reactions.

More severe anaphylactic reactions occur less frequently, approximately one in 20,0000–50,000 transfusions. However the onset of life-threatening signs and symptoms can be rapid.

The following mechanisms have been implicated in anaphylactic reactions (Callum 2011):

- IgA-deficient patients who have anti-IgA antibodies
- patient antibodies to plasma proteins (such as IgG, albumin, haptoglobin, transferrin, C3, C4 or cytokines)
- transfusing an allergen to a sensitised patient (for example, penicillin or nuts consumed by a donor)
- rarely the transfusion of IgE antibodies from a donor to an allergen present in the recipient.

Investigation of severe and anaphylactic-type allergic reactions should include testing for IgA deficiency and/or antibodies on a pre-transfusion specimen. Post-transfusion tryptase levels may also help to determine whether a reaction is allergic.

Treatment will depend on the degree of severity of signs and symptoms.

Case study: Allergic

A 67-year-old woman (blood group O positive) recently diagnosed with leukaemia had a platelet count of 27 and was receiving a unit of group O positive apheresis platelets prior to insertion of Hickman catheter. The platelets were administered over approximately 20–30 minutes.

At the end of the transfusion, the patient complained of itchiness and developed a rash over her abdomen and legs. She had no shortness of breath or stridor at this time. She was administered cetirizine and paracetamol.

Following this, she started to complain of feeling unwell with blurred vision. Vital signs were checked and she was found to have significant hypotension which led to a MET call.

The patient was treated with fluids and adrenaline and transferred to ICU. Within two hours her signs and symptoms were resolving.

On review, the patient stated she had not received blood products previously and had no known allergies. There was no clerical error and the patient was typed with the expected ABO group.

An IgA level taken on a pre-transfusion specimen was normal and tryptase was elevated post-transfusion (19.7ud/L).

Bacterial cultures of the patient were negative, the platelet bag was unable to be tested, and the screening by the Blood Service did not return an 'initial machine positive' result.

Minor allergic reactions can develop into more serious reactions, particularly if the product is administered quickly. If the transfusion is routine, consider administering the product at a slower rate and monitoring the patient closely.

In patients experiencing moderate to severe allergic reactions, an IgA level to confirm if the patient is IgA deficient is recommended.

A patient who has had previous allergic reactions to blood products and is IgA deficient with IgA antibodies may require special blood products for future transfusions.

Acute haemolytic reaction

In the 2014–15 reporting period there were no reports of acute haemolytic reactions.

STIR guideline

HTR is clinically suspected if one or more of the following is present with a positive direct antiglobulin test (DAT) post-transfusion and an incompatible red cell cross match:

- fever and/or other symptoms of a haemolytic reaction (including dyspnoea, hypotension, tachycardia, back pain)
- failure to achieve expected rise of the Hb post-transfusion or a drop in Hb > 20g/L within 24 hours (excluding all causes for ongoing bleeding)
- rise in LDH > 50 per cent within 24 hours
- rise in bilirubin, free haemoglobin (plasma or urine).

Acute haemolytic transfusion reactions occur in one in 76,000 transfusions and may be associated with:

- ABO/Rh mismatch
- atypical (non-ABO) red cell alloantibodies as a result of patient immunisation from previous pregnancy or transfusion
- rare cases when group O donor platelets containing high titres of anti-A and/or anti-B are transfused to a non-group O recipient

Haemolytic transfusion reaction involves immunologic destruction of transfused red cells, due to incompatibility of antigen on transfused cells with antibody in the recipient circulation <transfusion.com.au>.

Transfusion-transmitted infection, including bacterial sepsis

For the reporting period 2014–15, there were no reports of transfusion-transmitted infections (TTI), either bacterial or viral.

STIR guideline

A TTI should be reported if the recipient has evidence of infection post-transfusion and there was no evidence of infection with the agent of infection prior to transfusion, and:

- at least one component received by the recipient was donated by a donor who had evidence of the same transmissible infection, or
- at least one component received by the recipient was shown to have been contaminated with the agent of infection.

These may be reported via the bacterial/other form for all bacterial, parasitic (such as malaria) or other infections, not including serious viral infections.

Use the viral infection form for viral infections such as HIV, hepatitis or CMV.

The risk of bacterial transmission following transfusion of platelets and red cells is the most common infectious risk of transfusion. International data indicates the risk of clinically apparent reactions to be at least one in 75 000 for platelets and one in 500 000 for red cells (Kirby 2014).

During 2013 bacterial screening by the Blood Service of 124,381 platelets identified 120 (0.1 per cent) as confirmed positive. *Propionibacterium* spp. followed by coagulase-negative Staphylococcus (CNS), which are common skin contaminants, were the most frequently isolated organisms. These organisms are rarely, if ever associated with septic transfusion reactions in recipients, but may lead to intravascular catheter-associated bacteraemia, particularly in immunocompromised patients.

A small number of clinically significant organisms including *Streptococcus agalactiae* and *Streptococcus pneumoniae* were also detected. No cases of septic transfusion reactions were identified in patients who received platelets (Transfusion Transmissible Infections in Australia 2014).

The Blood Service has put in place a number of strategies to reduce the risk of bacterial contamination. These include:

- pre-donation health screening – donor questionnaires asking specific questions related to identified risks for bacterial contamination
- donor skin disinfection
- flow diversion techniques – diverting the first part of the collection away from the collection bag, shown to reduce the bacterial load by up to 70 per cent
- process control – following the principles of Good Manufacturing Practice
- bacterial pre-release testing – since 2008 all platelets tested.

Other infectious agents

Although representing only 16 per cent of the donor population, first-time blood donors contributed 80 per cent of TTIs in Australia in 2013. This ratio has been fairly consistent over the period from 2005–2013, highlighting the importance of promoting education of potential new donors and appropriate self-deferral (Kirby Institute 2014).

In the Blood Service's *Transfusion Transmissible Infections in Australia 2014* surveillance report, no transfusion-transmitted HIV, HCV, HTLV or syphilis infections were reported during 2008–2013. Three probable cases of transfusion-transmitted HBV infection were reported in the 2008–2013 period, two in 2009 associated with the same donor and one further case in 2011 (Kirby Institute 2014). The Blood Services estimated residual risks is noted in Table 10.

Table 10: Residual risk estimates calculated on Blood Service data

Agent and testing standard	Window period	Estimate of residual risk 'per unit' (a)
HIV (antibody/p24Ag + NAT)	5.9 days	Less than 1 in 1 million
HCV (antibody + NAT)	2.6 days	Less than 1 in 1 million
HBV (HBsAg + NAT)	15.1 days	Less than 1 in 1 million
HTLV 1 and 2 (antibody)	51 days	Less than 1 in 1 million
vCJD [No testing]		Possible, not yet reported in Australia
Malaria (antibody)	7–14 days	Less than 1 in 1 million

Notes: vCJD = variant Creutzfeldt-Jakob Disease; (a) The risk estimates for HIV, HTLV and HCV are based on Blood Service data from 1 January 2013 to 31 December 2014. As no HTLV incident donors were recorded for the period, the residual risk estimate was derived from one model only and based on first-time donor risk calculation. The HBV WP and OBI risk function have been estimated using Blood Service data from 1 January 2014 to 16 April 2015. See <www.transfusion.com.au/adverse_events/risks/estimates#sthash.aG2iL2X8.dpuf>.

For infectious diseases where there is no effective testing, donor health screening is important to recognise those at risk and defer donation, for example, Zika virus and travel deferrals.

Transfusion-associated circulatory overload (TACO)

Data summary – validated data Transfusion-associated circulatory overload, n = 9			
Gender		**Time of transfusion**	
Male	5	In hours	4
Female	4	Out of hours	5
Age		**Imputability**	
< 1 year	0	Certainly	2
1–18 years	0	Probably	6
19–29 years	0	Possibly	1
30–49 years	1	Excluded	
50–69 years	2	Not assessable	
70–79 years	4	**Severity**	
80+ years	2	SR1: unexpected death or a permanent and disabling injury	
Blood product implicated			
Red cells	4	SR2: temporary loss of function	6
Platelets	2	SR3: increased treatment, but no increased length of stay	3
FFP	1		
Cryoprecipitate	0	SR4: no injury or minor requiring only first aid treatment	
Multiple products	2		
		Not assessable	

STIR guideline

Cases of TACO are confirmed by any four of the following occurring within four hours of transfusion:

- acute respiratory distress
- tachycardia
- increased blood pressure
- acute or worsening pulmonary oedema evident on chest X-ray
- evidence of positive fluid balance.

The following cases should also be reported:

- cases where TACO is suspected even if the available information suggests that fewer than four of the five defining criteria for TACO are met
- cases with features of TACO which occur between six and 24 hours should also be reported.

Risk factors for TACO include being at an extreme of age, having pre-existing cardiac and/or (potential) renal dysfunction, acute myocardial infarction, and individuals receiving plasma. TACO is an under-recognised yet important clinical entity associated with high mortality and morbidity (Alam 2013).

On investigation, crackles may be heard on chest auscultation and chest X-ray may show signs of chronic heart failure: bilateral infiltrates and an enlarged cardiac silhouette.

An elevated pulmonary capillary wedge pressure (PCWP) and central venous pressure (CVP) may also be helpful in confirming a diagnosis, although they are rarely available.

New data suggests that the use of B-type natriuretic peptide (BNP) is helpful in confirming the diagnosis of TACO, despite not having standardised parameters to define it (Alam 2013).

The 2011 Food and Drug Administration report on transfusion-related mortality indicated that TACO was the second-most commonly reported cause of death next to transfusion-related acute lung injury (TRALI) (Alam 2013). According to the 2015 annual Serious Hazards of Transfusion Report (SHOT), TACO was reported to be a contributory factor in the death of seven patients (n = 89 reports), while 34 patients developed major morbidity.

Alam et al. suggest that a pre-transfusion risk assessment should be undertaken, including a detailed assessment of cardiac, respiratory and renal function. A simple assessment tool is included in the article.

Blood Matters has designed a risk assessment tool for health services, based on the SHOT tool available in the 2015 report. This can be found on the Blood Matters website: <www2.health.vic.gov.au/hospitals-and-health-services/patient-care/speciality-diagnostics-therapeutics/blood-matters>

Case study: TACO

A 72-year-old man with newly diagnosed acute myeloid leukaemia (AML) (day 16 post-chemotherapy) was receiving a unit of platelets.

During the post transfusion observations (unit run over one hour), the patient was found to have a significant drop in O2 saturation (79 per cent on room air, down from 93 per cent) and a MET call was made.

A chest X-ray at the time showed overload.

The patient was administered diuretics and admitted to ICU for management of acute respiratory distress related to overload or sepsis.

The patient was also found to have a significant troponin rise at this time. He went on to have further blood products with diuretic cover without issue.

Transfusion-related acute lung injury (TRALI)

There were no validated reports of TRALI for 2014–15.

STIR guideline

All cases of TRALI should be reported to the Blood Service at the first available opportunity so that products associated with the donation can be quarantined and tested to prevent potential reactions in other recipients.

Clinical TRALI features:

- acute respiratory distress with hypoxia
- bilateral pulmonary infiltrates, evidenced on radiology imaging
- occurs during or within six hours of transfusion
- no other apparent cause of acute lung injury (ALI)
- no evidence of TACO.

The National Blood Authority's Australian Haemovigilance Scheme received 24 reports of suspected episodes of TRALI in the period 2008–13, with only three cases confirmed.

The Australian haemovigilance report for 2013–14 included three reports of TRALI. Imputability was not assessable for one report, and the other two were likely/probable.

All suspected cases of TRALI should be reported to the Blood Service so that other products associated with the implicated donor can be recalled, and for donor follow-up.

Since the introduction of male-only plasma for clinical use in 2007 and 100 per cent male only plasma achieved in 2012, reports of TRALI to the Blood Service have decreased.

Delayed haemolytic reactions

Data summary – validated data Delayed haemolytic, n = 10			
Gender		**Imputability**	
Male	4	Certainly	0
Female	6	Probably	7
Age		Possibly	3
< 1 year	0	Excluded	
1–18 years	0	Not assessable	
19–29 years	0	**Severity**	
30–49 years	2	SR1: unexpected death or a permanent and disabling injury	
50–69 years	2		
70–79 years	5	SR2: temporary loss of function	1
80+ years	1	SR3: increased treatment, but no increased length of stay	8
Blood product implicated			
Red cells	10	SR4: no injury or minor requiring only first aid treatment	1
Platelets	0		
FFP	0	Not assessable	
Cryoprecipitate	0		

STIR guideline

Delayed reactions are usually delayed haemolytic reactions due to the development of red cell alloantibodies.

Delayed HTRs may present with unexplained fever, anaemia and/or jaundice, usually two to 14 days after transfusion of a red blood cell component.

The reaction may be confirmed by **one or more** of the following:

- a fall in Hb or failure of increment
- rise in bilirubin
- incompatible cross match not detectable pre-transfusion.

Simple serological reactions such as antibody development without a positive DAT or evidence of haemolysis are excluded.

Transfusion-associated graft versus host disease (TAGvHD)

There were no reports of TAGvHD in this reporting period.

There was one report (IBCT) where a patient requiring irradiated products received non-irradiated red blood cells.

At the time of the report the patient (a neonate who had received intra-uterine transfusion) had not developed TAGvHD.

Health services need to ensure processes are in place to assist staff to recognise patients at risk of TAGvHD, and ensure they receive irradiated products.

STIR guideline

The development of the classical symptoms of fever, rash, liver dysfunction, diarrhoea and pancytopenia occurring one to six weeks following transfusion, without other apparent cause.

The diagnosis is supported by skin/bone marrow biopsy appearances and the presence of circulating donor lymphocytes.

Post-transfusion purpura (PTP)

There were no reports of PTP for this reporting period.

PTP is not a common reaction. In the 2015 Australian haemovigilance report, there were only three reports over a five-year period, giving an incidence of less than one per cent of reported reactions.

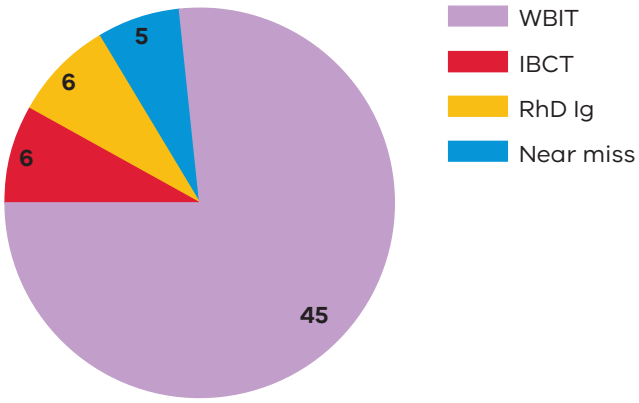
STIR guideline

PTP is characterised by sudden and self-limiting thrombocytopenia (typically platelet counts < 10 x 109/L) arising five to 12 days following transfusion of red cells or platelets. It is associated with the presence of antibodies directed against the human platelet antigen (HPA) system.

Procedural reports

The number of reported procedural events for 2014-15 is shown in Figure 7.

Figure 7: Procedural events reported 2014–15



Incorrect blood component transfused (IBCT)

Data summary – validated data Incorrect blood component transfusion, n = 6			
Gender		**Time of transfusion**	
Male	4	In hours	4
Female	2	Out of hours	2
Age		**Imputability**	
< 1 year	1	Certainly	5
1–18 years	0	Probably	1
19–29 years	0	Possibly	
30–49 years	2	Excluded	
50–69 years	3	Not assessable	
70–79 years	0	**Severity**	
80+ years	0	SR1: unexpected death or a permanent and disabling injury	0
Blood product implicated			
Red cells	4	SR2: temporary loss of function	0
Platelets	1	SR3: increased treatment, but no increased length of stay	3
FFP	1		
Cryoprecipitate	0	SR4: no injury or minor requiring only first aid treatment	3
		Not assessable	0

Table 11: Types of IBCT events, 2014–15

Category	Number reported
Antigen or antibody issues	2
Components that did not meet specific requirements for patient	1
Inappropriate platelet/plasma product	1
Inappropriate red cell product	0
Incorrect blood component to incorrect patient	
ABO compatible	1
ABO incompatible (FFP)	1

STIR guideline

This includes reports of incidents in which:

- the component did not meet the specific requirements for the patient
- transfusion of a component intended for another patient (ABO compatible)
- ABO incompatible transfusions (due to any cause)
- transfusion of product other than that prescribed (for example, platelets instead of FFP)
- unnecessary or inappropriate transfusion.

This does not include RhD immunoglobulin administered to the wrong patient or inappropriately. RhD immunoglobulin errors should be reported via the specific RhD immunoglobulin form.

In this reporting period there were six reports of IBCT (Table 11).

There were no ABO incompatible red cell transfusions, however there were two incidents were Rh incompatible blood was dispensed and administered.

In both cases laboratory systems did not pick up the discrepancy in groups. In one case at least, there were two missed opportunities in the laboratory to pick up the error, one at time of cross match and the other when dispensing. A further opportunity to recognise the error was missed at the bedside where the discrepancy was not detected during the blood checking and administration process, and the blood was transfused.

Orders for transfusion need to be clear and unambiguous.

In one incident although the order was for platelets the nursing staff interpreted the order to be for red cells, which were then requested and administered. In another incident, which was reported as a near miss, the patient received three bags of platelets over two shifts where the prescription requested ‘five units pooled platelets’.

The intention was for one bag of platelets and was only picked up when laboratory staff questioned the need for this many bags of platelets.

Clarity regarding the product and any special requirements is important to ensure that the product administered meets the patient's requirements. Any uncertainty about the order should be clarified prior to collection of the blood product from the laboratory or blood fridge.

Case study: IBCT

A male patient in ICU following multi-trauma required transfusion of red cells for anaemia associated with traumatic blood loss.

The laboratory had previously performed a group and screen for the patient which determined his blood group to be A Rh negative, with negative antibody screen.

On request for two units of red cells an electronic cross match was performed. The scientist selected two units of A Rh positive blood and subsequently prepared these for the patient.

There were no alerts in the system to warn the scientist of the discrepancy. The units were dispensed by the laboratory, again without recognition of the discrepancy, with no alerts available.

The units were transfused on consecutive days without any of the clinical staff involved in the checking process either recognising and/or questioning the discrepancy in blood group.

The patient went on to develop an anti-E antibody which was identified during post-transfusion testing.

The health service has added a rule to the laboratory information system. When RhD positive red cells are selected for a patient who is RhD negative an alert will state: 'The product blood group selected is compatible but not the first choice for the patient'.

Wrong blood in tube

Data summary – validated data Wrong blood in tube, n = 56			
Gender		**Sample collected**	
Male	25	In hours	37
Female	31	Out of hours	19
Age		**Urgency of transfusion**	
< 1 year	13	Emergency	12
1–18 years	2	Routine	38
19–29 years	9	Unknown	6
30–49 years	10	**Location**	
50–69 years	9	Theatre	2
70–79 years	5	Ward	16
80+ years	8	ICU	3
		Ambulatory care	0
		Emergency department	11
		Maternity/delivery suite	21
		Home transfusion	0
		Other	3

STIR guideline

These events have the potential to cause harm to patients, because while labelling is consistent and passes zero-tolerance guidelines, the blood group may be different from that of the named patient.

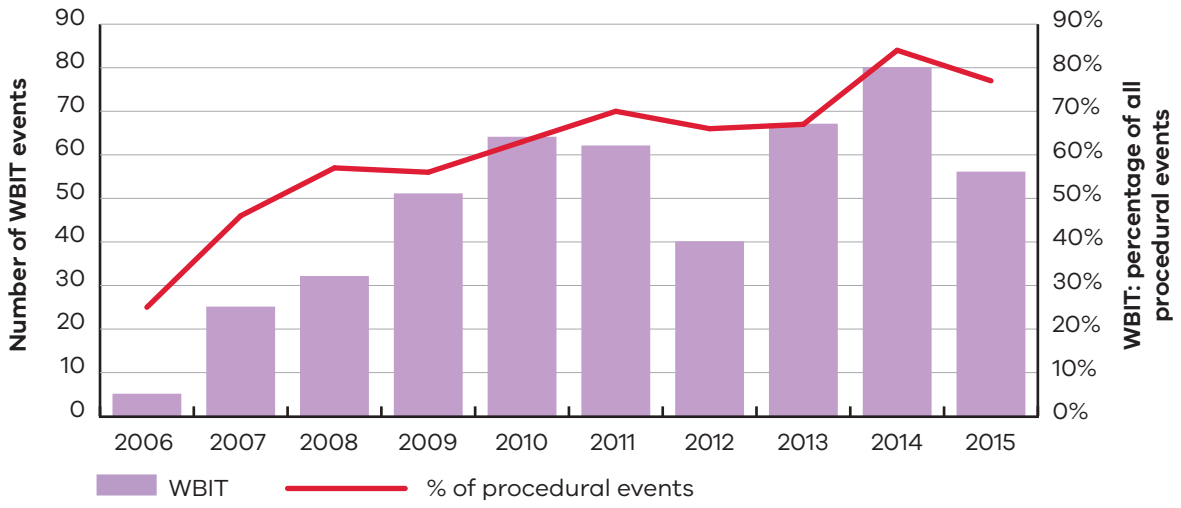
This includes specimens where:

- the sample is taken from the wrong patient but labelled as per the intended patient, or
- the sample is taken from the intended patient but labelled as per another patient.

From January 1, 2015 WBIT reporting was changed to exclude specimens where a discrepancy between the identification on the request and sample was detected, as these errors should be picked up and the specimen rejected where zero tolerance is enforced.

WBIT remains proportionally the most common procedural event reported to STIR, and in 2014–15 the WBIT category received the largest number of reports (Figure 8).

Figure 8: Number of WBIT/year and percentage of all procedural events reported



WBIT events may occur when:

- pre-printed labels are used (where permitted by health service policy) and not checked correctly before application
- specimens are not labelled at the patient's side
- patient identification is not checked correctly due to:
  - patient familiarity
  - use of other identifiers such as bed number
  - lack of an identification band.

Figure 9: Factors contributing to WBIT incidents (multiple responses per event)

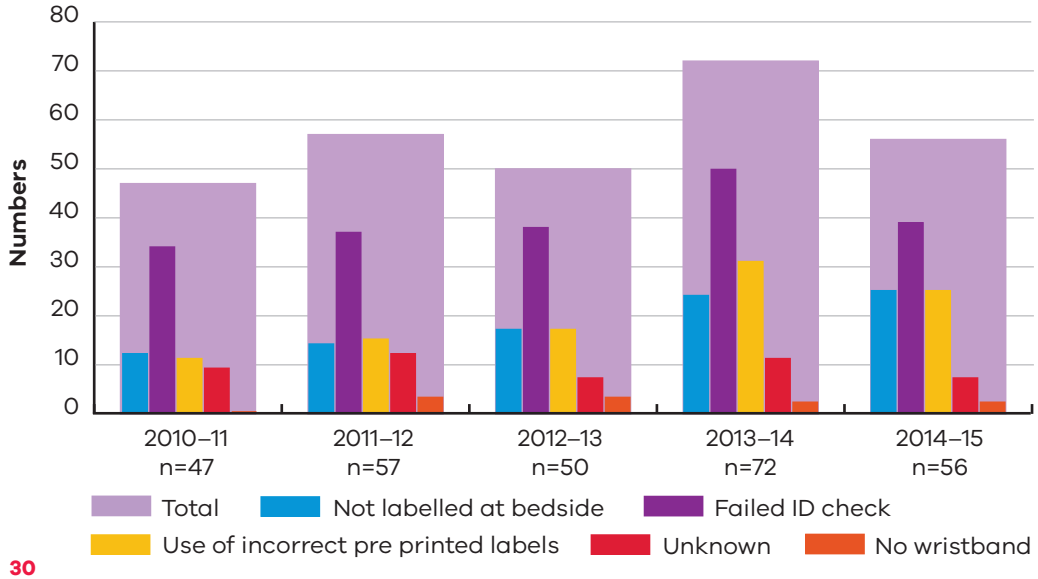


Figure 9 highlights the factors contributing to the reported WBITs, with Figure 10 outlining the area where these WBITs occurred. Table 12 describes how these incidents were discovered.

Some areas are at greater risk of a WBIT due to the type of patient and/or the work environment, for example emergency departments and maternity areas, where the workload is unpredictable and often rushed.

The risks include patients:

- who are unable to assist in the identification process
- patients who are unidentified or without an identification band.

Figure 10: Where WBIT errors occur

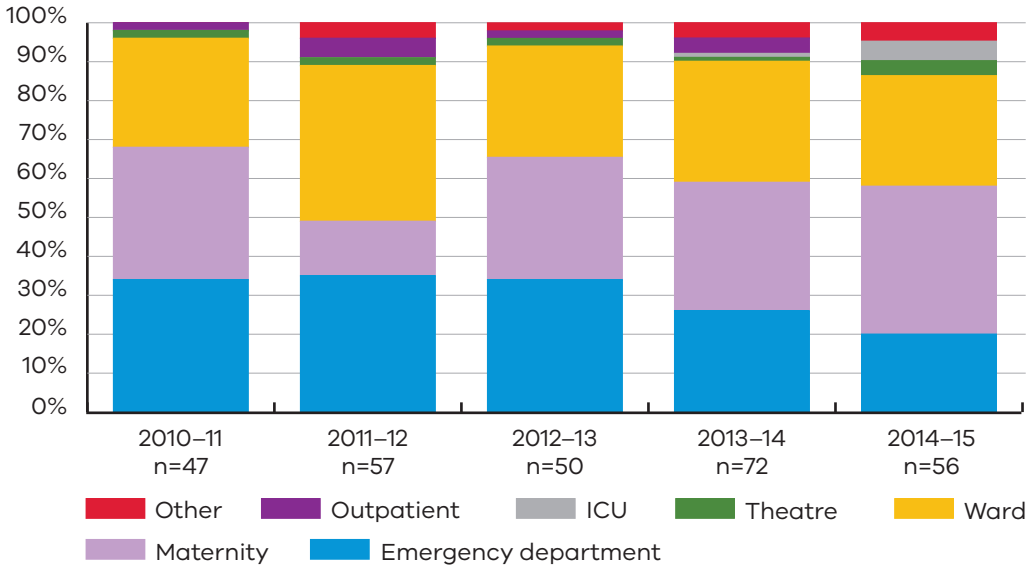


Table 12: How the incident was discovered, 2014–15

Category	Number	Percentage (%)
Recognised prior to testing	29	52%
Discrepancy noted when comparing sample results with historical record	21	38%
Recognised post testing but prior to issue	4	7%
Significant change in MCV compared with prior testing	3	5%
Recognised post issue but prior to transfusion	2	4%
Other	3	5%
Total	**56**	

Note: More than one response may be selected per incident.

Measures to prevent WBIT errors include:

- **Zero tolerance for blood banking specimens**. WBIT errors are estimated to affect approximately one in 2,000 samples (Gonzalez-Porras, Graciani et al. 2008). Mislabelling of samples occurs more often, affecting, on average, one in 40 samples (Murphy and Kay 2004). Zero tolerance needs to be enforced by the laboratory and supported by administration to ensure collecting staff identify their patients correctly, and to prevent clinical staff pressuring laboratory staff into accepting mislabelled samples.
- **Education of staff involved in specimen collection**. Many staff are involved in specimen collection, including nursing, medical and phlebotomists. The largest proportion of WBITs reported to STIR is collected by nursing staff. This may be because they collect more specimens than medical staff. However, phlebotomists, who would be expected to collect the greatest number of specimens, are responsible for collecting the smallest proportion of WBIT samples. This may be due to the fact that specimen collection is their sole focus and they have fewer distractions than other groups when performing this task.
- Fifty per cent (n = 28) of staff responsible for collecting a reported WBIT had received some education about this task. For a large proportion, education undertaken was unknown, with only approximately five per cent (n = 3) of WBIT collectors having no training recorded. The type of training was most frequently a hospital-based induction, learning package or in-service. This type of training is often once only and health services may need to consider implementing regular education sessions for staff who perform this critical task infrequently or sporadically.
- **Self-reflection for staff involved in a WBIT**. This allows staff to reflect on the error, how it occurred, and what can be done to prevent it occurring again. Clinical governance or risk management staff can gain insight from the staff making these errors about how and why they occur, and may be able to implement process improvements to reduce the risk of these errors for other staff.
- **Technology to improve patient identification and specimen labelling**. Technological advances employing barcode scanning to improve patient identification at specimen collection and blood administration are available and should be considered. Care should be taken when implementing these systems to ensure new risks associated with the technology are not introduced.

RhD administration

Data summary – validated data RhD immunoglobulin, n = 6			
Gender		**Intended administration**	
Male	0	Routine prophylaxis	1
Female	6	Sensitising event	2
Age		Post natal	3
< 1 year	0	**Type of incident**	
1–18 years	0	Administered, not required (Rh negative mother with Rh negative baby)	
19–29 years	2	Administered to Rh positive woman	2
30–49 years	4	RhD dose omitted	1
50–69 years	0	Delay in administration (>72 hrs.)	
70–79 years	0	Wrong or inadequate dose	
80+ years	0	Storage and handling error (near miss)	1
Location		Other: released to incorrect patient (near miss), reaction	2
Hospital	6		
Community	0		
General Practitioner	0		
Other	0		

STIR guideline

Includes incidents related to RhD immunoglobulin request, administration for women of child bearing potential or following transfusion of RhD mismatched red cells or platelets.

This includes incidents where:

- RhD immunoglobulin is omitted or administered late
- RhD immunoglobulin is administered to a RhD positive woman
- RhD immunoglobulin is administered to a woman with immune RhD antibody
- RhD immunoglobulin is administered erroneously to the mother of a RhD negative infant
- RhD immunoglobulin is administered to the wrong patient
- the incorrect dose of RhD immunoglobulin is administered
- failure of prophylaxis
- an expired product is administered.

Reporting of incidents related to RhD immunoglobulin is a new category for STIR, with reporting commencing in January 2015. Six months of data is included in this report. The RhD immunoglobulin form covers incidents related to administration and prescribing errors. There were six incidents reported this reporting period.

All the reported incidents occurred in the hospital environment with ward staff detecting the majority of errors.

In two incidents an Rh positive woman was administered RhD immunoglobulin. In one report the pre-administration checks failed to identify that the patient details attached to the product did not match those of the patient receiving the product. In the second report, RhD immunoglobulin was prescribed, dispensed and administered without any confirmation of patient blood group.

There was one report of a reaction to RhD immunoglobulin in a patient requiring a large intravenous dose for a foetomaternal haemorrhage. There was insufficient information in the report to determine the type of reaction or imputability of the product. These reactions will not be accepted as part of this reporting as they should be reported to the manufacturer and the Blood Service. We wish to minimise the reporting requirements to health services where there is already good reporting available.

There is some evidence suggesting that intramuscular administration of RhD immunoglobulin-VF in patients with a BMI > 30 is associated with decreased efficacy. As a precautionary measure, CSL Behring has incorporated additional information in the RhD immunoglobulin-VF product information recommending that the clearance of foetal cells and the presence of RhD immunoglobulin are confirmed post administration in this patient group (<transfusion.com.au/blood_products/fractionated_plasma/immunoglobulins> updated 19 June 2015).

Currently there have been no reports to STIR of failure of RhD prophylaxis.

A checklist for RhD immunoglobulin administration has been developed, based on the SHOT RhD immunoglobulin Administration Flowchart v7, October 2012, and is available in Appendix 4.

Case study: RhD immunoglobulin

A 34-year-old woman received 250IU of RhD immunoglobulin post miscarriage at eight weeks.

The patient's blood group was AB positive.

The blood group had not been checked by the prescriber before writing the prescription, laboratory staff prior to dispensing the product, or the clinical staff prior to administering the product.

This incident has led to the laboratory changing its procedures. RhD immunoglobulin is no longer dispensed without the laboratory confirming the patient blood group, either through on-site testing or through receipt of a validated report from an external pathology provider.

Health services should have a system in place to check the patient blood group prior to dispensing RhD immunoglobulin.

This is particularly important where shared care arrangements are in place as the patient's blood group may not be available in the health service/pathology provider information system. Where blood group results from external laboratories are accepted, this should only be through receipt of a validated report from the provider.

Cell salvage

This new category of reporting was made available 1 January 2015. To date no reports have been received in relation to cell salvage. A letter has been sent to the Australian and New Zealand College of Perfusionists to introduce them to STIR and cell salvage reporting through STIR.

STIR guideline

Incidents and near misses involving the use of intraoperative and/or postoperative cell salvage where the incident may be due to:

- operator error
- machine failure
- administration error
- adverse reactions to the reinfused product.

Near miss

Data summary – validated data Near miss, n = 5			
Gender		**Time of incident**	
Male	2	In hours	3
Female	3	Out of hours	2
Age		**Urgency of transfusion**	
< 1 year	1	Emergency	4
1–18 years	0	Routine	1
19–29 years	0	Unknown	0
30–49 years	0	**Location**	
50–69 years	3	Theatre	0
70–79 years	0	Ward	1
80+ years	1	ICU	0
Blood product implicated		Ambulatory care	0
Red cells	4	Emergency department	3
Platelets	1	Maternity/delivery suite	0
FFP	0	Home transfusion	0
Cryoprecipitate	0	Other (NICU)	1

Table 13: Types of near miss events

Category	Number Reported
Inappropriate component issued	1
Labelling/documentation	1
Laboratory	0
Administration	2
Incorrect prescription or request for blood	1
Storage and handling	0

Near miss reporting has been declining since the 2011–12 STIR report, from 23 per cent of all reported procedural events to seven per cent in this report. Some near miss events may not be reported as staff do not recognise the value of reporting events where no harm is caused.

Health services should educate staff about the value of near miss reporting and follow-up to look for commonalities between the causes.

Case study: Near miss

Ward RN contacted pathology to request red cell units be prepared to go with a patient being transferred via ambulance to another hospital.

The RN only provided the patient's surname, which the scientist misheard (two patients in the same ward area with similar names had current cross matched red cells).

When the scientist repeated the incorrect patient surname the mistake was not corrected. Red cells cross matched for the patient (as understood by the scientist) were prepared and packed ready for transfer with the patient.

The 'Request for blood and blood products' form, sent to collect the units, had different patient details to the units and a request was made for a new form.

However the scientist was told by the ward RN that there was no time for this as the ambulance was ready to go.

The blood was sent despite the discrepancy in labelling and without further checks.

Prior to administration, the ambulance officers identified the error when performing patient and product checks and did not transfuse the blood. There was no harm to the patient in this instance.

It is important that patient identification is complete at all steps of the process. When ordering, collecting or administering blood products, three patient identifiers should be provided or confirmed: name, date of birth and UR number (address where UR number not available), rather than name alone.

Incorrect, incomplete or omission of patient identification continues to be a contributing factor to near miss, WBIT and IBCT events. Health services should continue to educate staff regarding the correct process for patient identification for all staff involved in the transfusion chain.

Sentinel events

The STIR Expert group reviewed one sentinel event related to the death of a woman experiencing a postpartum haemorrhage.

After review the Expert group determined the death was due to causes other than lack of transfusion.

No other transfusion related sentinel events were reported for this period.

Future

The Blood Matters team and the STIR Expert group are currently exploring options with the department in the process to upgrade the Victorian Health Incident Management System (VHIMS).

It is hoped that the upgraded system will allow some ability to cross reference reports and/or a system of notification or alert for STIR reportable incidents and events.

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Appendix 1: Expert group members 2014–15

Amanda Davis, (chair) Consultant Haematologist, Alfred Health, Victoria

Christine Akers, (secretary) Transfusion Nurse, Blood Matters Program, Victoria

Helen Atkinson, Transfusion Nurse, Royal Hobart Hospital, Tasmania

Gerald Bates, Laboratory Manager, Northern Tasmanian Pathology Service, Launceston General Hospital, Tasmania

Linley Bielby, Program Manager, Blood Matters Program, Victoria

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Bridget Glazebrook, Data Manager, Blood Matters Program, Department of Health, Victoria

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Chris Hogan, Medical Director Pathology Services, Australian Red Cross Blood Service

Giles Kelsey, Consultant Haematologist, Royal Melbourne Hospital, Victoria

Geoff Magrin, Scientist, Victoria

Ellen Maxwell, Director of Haematology, Melbourne Pathology, Victoria

Scott McArdle, Transfusion Nurse, Australian Red Cross Blood Service

Tina Noutos, Haematologist, Royal Darwin Hospital, Northern Territory

Richard Rogers, Blood Bank Scientist, Cabrini Health, Victoria

Erica Wood, Associate Professor, School of Public Health and Preventative Medicine, Monash University, Victoria

Anissa Yttrup, Transfusion Nurse, Barwon Health, Victoria

Theresa Williamson, Manager, Quality and Safety Programs, Department of Health, Victoria (resigned)

Jonathan Prescott, Acting Manager, Quality and Safety Programs, Department of Health, Victoria (resigned)

Carole Smith, Consultant Haematologist, Austin Hospital, Victoria (resigned)

Appendix 2: STIR publications and promotions

Cancer Nurses Society of Australia, Melbourne, July 2014. Poster: *Acute transfusion reaction knowledge and management – how well are we doing?*

HAA, Perth, October 2014. Posters: *A national haemovigilance framework for Australia: Could this be a reality?* and *What we know about the 3 R's of acute transfusion reaction: recognise, react and report.*

ISBT, London, June 2015. Poster: *Acute transfusion reaction: policy, management and knowledge.*

Serious Transfusion Incident Reporting guide 2015, <www.health.vic.gov.au/bloodmatters/stir.htm>.

Appendix 3: Imputability and severity scores

Imputability/causality	Definition
Not assessable	When there is insufficient evidence for an imputability definition.
Excluded	When there is conclusive evidence that the cause of the incident is attributable to other causes and not the transfusion.
Possibly	When the evidence is indeterminate for attributing the incident to either the transfusion or other causes.
Probably	When the evidence is clearly in favour of attributing the incident to the transfusion.
Certainly	When the evidence is conclusively attributable to the transfusion.

Severity	Incident
1	Relatively infrequent, clear-cut events that occur independently of a patient's condition; commonly reflect health service system and process deficiencies; result in, or have the realistic potential to result in, an unexpected death or a permanent and disabling injury or psychological harm to a person and includes reportable sentinel events.
2	Events that result in a temporary loss of function (sensory, motor, physiological or intellectual) which is unrelated to the natural course of the patient's illness and differ from the expected outcome of the patient's management.
3	Events that result in a person requiring increased treatment, but not hospitalisation or an increased length of stay.
4	Events that result in minor injury requiring only first aid treatment or no injury.

Appendix 4: RhD immunoglobulin administration checklist

Always confirm

- the woman's identity
- that the woman is RhD negative using the latest laboratory report
- that the woman does not have immune RhD immunoglobulin using the latest laboratory report
- that informed consent for administration of RhD immunoglobulin is recorded in notes. Administer product by deep IM injection. Care needs to be taken in patients with a high BMI (BMI > 30) regarding the site of injection, accessibility of the underlying muscle, and the length of the needle used

Potentially sensitising events (PSEs) during pregnancy	
First Trimester (≤ 12 weeks gestation)	
Chorionic villus sampling	Administer 250 IU RhD immunoglobulin (Ig) within 72 hours of event. Confirm product / dose / expiry and patient (ID) pre-administration.
Miscarriage	
Termination of pregnancy	
Ectopic pregnancy	
Second and third trimester	
Obstetric haemorrhage	Administer 625 IU RhD Ig within 72 hours of event. Confirm product / dose / expiry and patient ID pre-administration.
Amniocentesis / cordocentesis	
External cephalic version of a breech presentation, whether successful or not	
Abdominal trauma, or any other suspected intra-uterine bleeding or sensitising event	
All women should have the magnitude of potential foetomaternal haemorrhage assessed	Administer further RhD Ig, as appropriate, following discussion with laboratory. (A dose of 250 IU RhD Ig is sufficient to prevent immunisation by 2.5 mL of foetal red cells).

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Routine Antenatal RhD immunoglobulin Prophylaxis	
For routine antenatal RhD immunoglobulin prophylaxis (irrespective of whether RhD Ig already given for PSE)	Take a blood sample to confirm group and check antibody screen – do not wait for results before administering RhD Ig.
	Administer 625 IU RhD Ig at approximately 28 and 34 weeks gestation.
	Confirm product / dose / expiry and patient ID pre-administration.
At delivery	
Is the baby's group confirmed as RhD positive? or Are cord samples not available?	All women who deliver an RhD positive baby should have quantification of foeto-maternal haemorrhage.
	Administer at least 625 IU RhD Ig within 72 hours of delivery. Confirm product / dose / expiry and patient ID pre-administration.
Does the quantification of foetomaternal haemorrhage indicate further RhD Ig is required?	Administer more RhD Ig following discussion with laboratory. (A dose of 250 IU RhD Ig is sufficient to prevent immunisation by 2.5 mL of foetal red cells).

Based on the SHOT RhD immunoglobulin Ig Administration Flowchart v7, October 2012
RANZCOG College Statement: Guidelines for the use of RhD immunoglobulin in obstetrics in Australia, November 2015. Blood Matters December 2015.